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Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Veterinary Services

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 03-15

Subject: Availability of Specific Pathogen Free Eggs

To: Biologics Licensees, Permittees, and Applicants

Veterinary Services Management Team Directors, Center for Veterinary Biologics

In September 2003, an avian adenovirus outbreak affected production facilities of one of the three commercial suppliers of specific pathogen free (SPF) eggs. Under the terms of VS Memorandum No. 800.65, this outbreak disqualifies eggs from these flocks from use in the production of veterinary biologics. Commercial SPF egg supplies have already been affected by suspected avian leukosis virus contamination affecting a portion of the output from a second SPF egg supplier.

Taken together, these concurrent events have resulted in a critical reduction in the availability of SPF eggs that meet all the requirements of Veterinary Services Memorandum No. 800.65. The Center for Veterinary Biologics (CVB) has received comments regarding the emergency situation resulting from this reduction in SPF egg supply from the three commercial SPF egg producers, biologics manufacturers, and has held conference calls with representatives of the National Chicken Council, the National Turkey Federation, and United Egg Producers. These discussions have prompted the CVB to take the following actions, effective with the date of this notice:

- APHIS will allow SPF eggs from source flocks not meeting the criteria set forth in VS Memorandum No. 800.65, with respect to adenovirus exposure, to be used in the production of killed virus products for use in poultry. These eggs are not eligible for use in live products, non-poultry products, master seeds, or working seeds.
- The basis for this action is the critical reduction in the availability of SPF eggs
 for vaccine production, concern for future vaccine product availability, and
 support for this action by representatives of affected users of these vaccine
 products.

• Use of such eggs will be allowed until January 2, 2004. APHIS will closely monitor this emergency and reevaluate the situation by December 2, 2003, or earlier should events dictate. Licensees producing killed viral products for use in poultry who wish to use such eggs for production should submit written requests to the CVB. The additional testing and reporting requirements to mitigate the risks surrounding use of these eggs will be available from the CVB after October 8, 2003.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr. Director Center for Veterinary Biologics